

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.554, the Board of Pharmacy hereby amends Chapter 24, "Pharmacy Internet Sites," and Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

The amendments:

- Change the definition of "dispenser" to include nonresident pharmacies that dispense prescriptions for controlled substances in Schedules II through IV of Iowa Code chapter 124;
- Amend the requirement for reporting of those substances, contained in Chapter 24 regarding pharmacy Internet sites, to ensure that all pharmacies dispensing Schedules II through IV controlled substances to patients located in Iowa understand the requirement for reporting those prescriptions to the Iowa Prescription Monitoring Program (PMP);
- Identify those pharmacies that may be exempt from reporting to the Iowa PMP and establish processes for claiming such exemption; and
- Change prescription reporting frequency from twice monthly to weekly reporting and establish a timely reporting deadline.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the April 4, 2012, Iowa Administrative Bulletin as **ARC 0074C**. The Board received written questions, comments, and suggestions from the National Association of Chain Drug Stores (NACDS) regarding the proposed amendments. As a result of those questions, comments, and suggestions, the Board has changed the definition of "dispenser" to clarify that the term applies to a pharmacy located outside Iowa only if the pharmacy dispenses prescription drugs to a patient physically located in Iowa. The Board has also changed subrule 37.3(3), reporting periods, to provide flexibility in pharmacy reporting schedules. The change provides that if a pharmacy is currently on an alternative schedule of weekly submission of prescription dispensing records to another state's prescription monitoring program, the pharmacy may receive authorization from the PMP administrator to submit records to the Iowa PMP under that established schedule in lieu of the schedule defined by the subrule.

The amendments were approved during the June 27, 2012, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 124.552.

These amendments will become effective on January 1, 2013.

The following amendments are adopted.

ITEM 1. Amend subrule 24.3(3) as follows:

24.3(3) Iowa PMP. A pharmacy, wherever located, ~~within Iowa~~ that provides any controlled substance included in Schedules II through IV of Iowa Code chapter 124 to any patient within Iowa, unless the pharmacy is exempt from reporting pursuant to 657—subrule 37.3(1), shall report those dispensed prescriptions to the Iowa PMP as provided in rule 657—37.3(124).

ITEM 2. Amend rule **657—37.2(124)**, definition of "Dispenser," as follows:

"Dispenser" means a person who delivers to the ultimate user a substance required to be reported to the PMP database. "Dispenser" includes a pharmacy located outside the state of Iowa that is licensed by the board with a nonresident pharmacy license authorizing the pharmacy to dispense prescription drugs to patients physically located in Iowa. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.3(1).

ITEM 3. Amend rule 657—37.3(124) as follows:

657—37.3(124) Requirements for the PMP. Each dispenser, unless identified as exempt from reporting pursuant to subrule 37.3(1), shall submit to the PMP administrator a record of each reportable prescription dispensed during a reporting period. A dispenser located outside the state of Iowa, unless identified as exempt from reporting pursuant to subrule 37.3(1), shall submit to the PMP administrator a record of each reportable prescription dispensed during a reporting period to a patient located in Iowa.

37.3(1) Exemptions. The dispensing of a controlled substance as described in this subrule shall not be considered a reportable prescription. A dispenser engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in paragraphs 37.3(1)“a” or 37.3(1)“b” of this subrule shall so notify the PMP administrator and shall be exempt from reporting to the PMP.

a. A licensed hospital pharmacy shall not be required to report the dispensing of a controlled substance for the purposes of inpatient hospital care, the dispensing of a prescription for a starter supply of a controlled substance at the time of a patient’s discharge from such a facility, or the dispensing of a prescription for a controlled substance in a quantity adequate to treat the patient for a maximum of 72 hours. A hospital pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the hospital pharmacy dispenses only as provided by this paragraph.

b. A licensed pharmacy shall not be required to report the dispensing of a controlled substance for a patient residing in a long-term care facility or for a patient residing in an inpatient hospice facility. A pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the pharmacy dispenses only to patients residing in a long-term care facility or to patients residing in an inpatient hospice facility.

c. and d. No change.

37.3(2) No change.

37.3(3) Reporting periods. A record of each reportable prescription dispensed shall be submitted by each dispenser pursuant to the following schedule at least weekly. Records may be submitted with greater frequency than required by this schedule. This schedule defines minimum report frequency subrule. Records of reportable prescriptions dispensed between Sunday and Saturday each week shall be submitted no later than the following Wednesday. However, a pharmacy that is currently submitting prescription dispensing records to another state’s PMP on an alternative weekly reporting schedule may request authority to submit records to the Iowa PMP pursuant to that established schedule. The request shall be submitted in writing via e-mail, fax, or regular mail to the PMP administrator. The request shall identify the pharmacy by name, address, and Iowa pharmacy license number and shall define the alternative reporting period. The PMP administrator is hereby authorized to accept the pharmacy’s alternative weekly reporting schedule.

a. Records of reportable prescriptions dispensed between the first and the fifteenth day of a month shall be submitted no later than the twenty-fifth day of the month.

b. Records of reportable prescriptions dispensed between the sixteenth and the last day of a month shall be submitted no later than the tenth day of the following month.

37.3(4) and 37.3(5) No change.

[Filed 7/12/12, effective 1/1/13]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 8/8/12.